U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01325/96-001 Program Code 2110

Docket No. 030-01325

License No. 08-03604-03 Priority 1 Category G1

Licensee: Washington Hospital Center
110 Irving Street, N.W.
Washington, D. C. 20010-2975

Inspection Conducted: September 17,18,19,25, & 26, 1996

Inspectors: for Richard McKinley, Health Physicist — 10/30/96 Date

Teresa Hall Darden, Sr. Health Physicist — 10/30/96 Date

Approved By: M. Shanbaky — 10/31/96 Date
Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Branch 1

Inspection Summary: Routine, unannounced inspection conducted from September 17 thru 26, 1996 (Report No. 030-01325/96-001).

Areas Inspected: Organization/management oversight; inventory accountability and control of licensed materials; dosimetry; research; brachytherapy; and radiological safety training.

Executive Summary: Three apparent violations were identified: 1) failure to survey (Section 4); 2) loss of control of licensed material (Section 4); and 3) failure to notify the NRC (Section 4). Also, two unresolved items were identified during the inspection: 1) causes and reasons for the repeated failure to perform required bioassays by certain licensee individuals (Section 7.2) and 2) failure to train (Section 8.0).

DETAILS

1.0 Persons Contacted

+*Oliver Crump, Vice President, Ambulatory Services & Clinical Affairs (VPAS/CA)
+*Billy G. Bass, DSc., Radiation Safety Officer (RSO)
*Terry Lane, Health Physicist
Alesandro Ricci, Medical Physicist
*Roseanna Chan, PhD., Medical Physicist
Dinko Plenkovitch, PhD., Medical Physicist
*Michael Paidi, PhD., Principal Investigator
Judy Hannah, PhD., Researcher
Rui Lu, Researcher
*Gerald Johnston, M.D., Director, Nuclear Medicine/Chairman, Radiation Safety Committee
Diane Sweeny, M.D., Assistant Director, Nuclear Medicine
*Dennis Dionne, Administrative Director of Radiology Services
*John Zurita, Manager of Nuclear Medicine
Velma Mason, RN., Unit Nurse
Angela Cosby, RN., Clinical Nurse
John Mullaney, Certified Nuclear Medicine Technologist (CNMT)
Phillip Tompkins, CNMT
Beth Novak, CNMT
Trevor Subero, CNMT
Thomas Hilson, CNMT
Mark Narvaez, CNMT

* Present at first Exit
+ Present at second Exit

2.0 Scope of Program

Washington Hospital Center possesses a license of broad scope with activities that include research, nuclear medicine, radiopharmaceutical therapy and brachytherapy. Brachytherapy treatment is administered through sealed source implant as well as through use of a high dose rate afterloading device. Nuclear Medicine performs approximately 140 studies weekly, 1-3 of these studies involve the use of iodine-131 for therapy. In calendar year 1995, Radiation Oncology performed 70 brachytherapy studies; thus far in 1996, 46 brachytherapy studies have been performed.

3.0 Management Oversight

3.1 Radiation Safety Office

Oversight of the Radiation Safety Program is provided by the Radiation Safety Officer (RSO) in conjunction with the Radiation Safety Committee (RSC). Day to day oversight of radiation safety activities is provided by the Radiation Safety Office staff which is comprised of the RSO and a health physicist. The RSO reports to the Vice President of Ambulatory Services and Clinical Affairs (VPAS/CA). The inspector noted that audits of the nuclear medicine program were performed by a consultant service monthly and the audit reports were given to the RSO. The RSO stated that he responds to identified weaknesses and deficiencies and attempts to implement corrective action in a cooperative effort with users of radioactive material. The inspector discussed with the RSO and the VPAS/CA the apparent lack of success in achieving a lasting corrective action to prevent recurrence of identified program deficiencies. Based on the results of this inspection, both the RSO and the VPAS/CA concluded that although the cooperative effort of the RSO in correcting identified program deficiencies was generally successful, it was not adequate in preventing the recurrence of failure to perform the required bioassay on certain personnel (See Section 7.2).

3.2 Radiation Safety Committee

The established membership of the RSC meets the regulatory requirement for medical programs. From records review and personnel interviews, the inspector determined that the RSC met quarterly as required to discuss, evaluate and remedy radiation safety related problems. Records of the RSC meetings were maintained. Review of the RSC meeting minutes indicated that during the past year, much discussion was devoted to some issues, such as installation of a portal radiation monitor for waste leaving the facility and film badge problems relative to high dose readings of cardiac catheterization lab users (non-NRC). Relatively limited discussion was devoted to the loss of a 280 microcurie iodine-125 seed (See Section 4.0) and repetitive deficiencies in the performance of bioassays by Nuclear Medicine personnel were not discussed (See Section 7.2). The importance of RSC review of radiation safety related problems as well as oversight for implementing lasting corrective actions in achieving an effective program was discussed with the RSO, the RSC Chairman and other management representatives during the inspection. The licensee's VPAS/CA stated that although program oversight is good, he affirmed that a more aggressive approach will be used to ensure against repeated failures to follow the procedural requirements (See Section 7.2).

4. Inventory Accountability and Control of Licensed Materials

From observation, discussions with personnel, and review of records, the inspector noted that licensed materials receipts and inventory

accountability were generally well controlled. Licensed materials were observed being delivered to the Nuclear Medicine Hot Lab, surveyed, recorded, and either delivered to or picked up by users. Licensed materials receipts and transfer records were maintained. The records were audited monthly by Radiation Safety staff to assure compliance.

The recent increase in the number of patients who have been prescribed iodine-131 therapy doses that exceed activities of 150 milliCuries (mCi) and the possibility of exceeding the possession limits of the license were discussed with the RSO. The possession limits for the license for 10 CFR 35.300 radiopharmaceuticals is 400 mCi per radionuclide. The RSO stated that from his review of inventory on hand at any one time, that the possession limits of the license were never exceeded. However, he said that since doses can exceed 200 mCi, and there may be more than one patient administration during overlapping time intervals, he plans to apply to amend the license to increase possession limits.

From review of records the inspector learned of the loss of control of licensed material. Personnel interviews revealed the following:

> On February 22, 1996, 89 iodine-125 seeds with 0.28 mCi (280 microcuries [μCi]) activity each were received by Radiation Oncology for a prostate implant. The implant is a surgical procedure and was performed in the operating room under sterile conditions. The medical physicist and radiation safety personnel were present. The medical physicist stated that he loaded all the required seeds into the "Technar Template", a specially designed device that held the seeds into a specific configuration with the seeds positioned at selected coordinates to be inserted in the patient. He indicated that he was sure that no seeds were missing from the Template configuration when the urologist received it for patient implant. Further, the medical physicist said that as the urologist was inserting the seeds, the urologist noticed and stated that one of the seeds was missing. The medical physicist said that "because of sterile conditions, at the time nothing could be done about searching for the iodine-125 seed". However, upon completion of the surgical procedure, the health physicist performed a survey of the area. The survey also included a bag that had been placed under the patient in order to capture all waste associated with the prostate implant. Also surveyed were the associated linens, the floor and the chair in which the patient was placed upon completion of the implant. The inspector asked if the survey included all personnel involved in the procedure as well as their operating room clothing. The medical physicist responded that neither he nor the urologist were surveyed prior to leaving the operating room. Also, the health physicist said that surveys were not performed of the complete waste stream that left the operating room which includes scrub clothes and foot covers discarded by the urologist and other individuals associated with the surgery. The inspector also noted that the survey record did not identify the instrument(s) used. The RSO could not recall which of two instruments were used, the GM with the pancake probe, which is directionally sensitive or the sodium iodide crystal which could

provide a better sensitivity for general area radiation levels, or if both instruments were used.

Since the survey did not include all involved personnel, or the clothing they wore while in the operating room, the inspector concluded that an adequate survey was not performed in the attempt to account for or locate the missing iodine-125 seed.

10 CFR 20.1501 requires, in part, that each licensee make, or cause to be made, surveys that may be necessary for regulatory compliance and are reasonable under the circumstances to evaluate the extent of concentrations or quantities of radioactive materials and the potential radiological hazards that could be present.

Failure to perform adequate surveys that were necessary and reasonable under the circumstances to locate a 280 μCi iodine seed is an apparent violation of 10 CFR 20.1501.

When the RSO was asked why the NRC had not been notified of the loss of the licensed material, he said that he did not notify the NRC of the loss of the 280 μCi iodine seed because he misread the Part 20 Appendix C quantities required for reporting. 10 CFR 20.2201 requires, in part, that within 30 days of the licensee's knowledge of the lost or missing licensed material in quantities greater than 10 times the quantity listed in Appendix C to Part 20 that is still missing be reported (to the NRC) at this time with a written report required within 30 days of the telephone report. The quantity listed in Appendix C for iodine-125 is 1.0 μCi. Therefore, any loss greater than 10 microcuries was required to be reported. The missing quantity was 280 μCi.

The loss of control of licensed material is an apparent violation of 10 CFR 20.1802.

Failure to notify the NRC of the loss is an apparent violation of 10 CFR 20.2201.

5. Research & Development

The inspector toured the area where radioactive research is performed and, by observation and personnel interviews, verified the following: Research is conducted by the Medlantic Research Institute in the George Hyman Memorial Research Building, and at the Medlantic Outpatient Research Facility. In-vitro studies are performed in two laboratories using hydrogen-3, carbon-14, and iodine-125. The inspector verified that licensed material was ordered through Nuclear Medicine according to licensee procedure. Iodine-125 was ordered in 5 mCi lots and used in μCi amounts. Two iodinations were performed, thus far, in 1996 in a properly ventilated hood, in a filtered glove box. Small amounts of liquid waste were disposed to the drain. Solid waste was removed by the Radiation Safety Office and sent to a authorized disposal facility.

The RSO explained that, in the near future, human trials will begin on cardiology patients. The research will be done by cardiologists working under the supervision of an authorized radiation oncologist. The trials involve a process called Rhennostosis. The process will use phosphorus-32 (P-32) and/or strontium-90 (Sr-90) stents. The licensee stated that the users for these procedures will be trained prior to initiating these activities.

6. Brachytherapy

The brachytherapy program was reviewed by the inspector. The inspector learned that brachytherapy is accomplished by the use of a high dose rate afterloader (HDR), temporary implants with cesium-137, permanent implants with iodine-125 and palladium-103 seeds, and a strontium-90 eye applicator.

Except for the loss of control of an iodine-125 seed (Discussed in Section 4), no health or safety concerns or violations were identified in the brachytherapy program.

7.0 Personnel Dosimetry

7.1. External Dosimetry

The licensee's procedures require that personnel who are likely to receive in excess of 10 percent of applicable limits be issued appropriate whole body and/or extremity dosimeters. From observation of personnel who handled licensed material, the inspector noted that all were wearing dosimetry.

All personnel doses were well below the regulatory dose limits.

7.2. Internal Dosimetry

From personnel interviews and records review, the inspector learned that in accordance with 10 CFR 35.75, during 1995 the licensee administered approximately 42 therapeutic doses of iodine-131 greater than 30 mCi each. Thus far in 1996, 33 therapeutic doses have been administered. Actual doses during 1995 and through September 19, 1996, ranged from 126 mCi to 280 mCi. 10 CFR 35.315(a)(8) requires that all persons who help prepare or administer iodine-131 to patients hospitalized in compliance with 10 CFR 35.75 are required to have their thyroid burdens measured within 3 days of preparation and/or administration. The inspector noted that staff was knowledgeable of the bioassay requirement. However, there was no consensus among them about the length of time that should elapse after dose preparation/administration and initial time that the bioassay should be performed. The RSO said his criteria was that the bioassay be performed no earlier than 24 hours after assisting with preparation and/or administration of iodine-131 therapy doses, and this would be clarified in an upcoming training class.

The inspector examined records of thyroid bioassays performed following 42 iodine-131 administrations completed in 1995. In 18 iodine-131 administrations, at least one individual who assisted in the therapy and was required to have a thyroid bioassay failed to do so. In 7 cases, the Director of Nuclear Medicine/Chairman of the Radiation Safety Committee failed to have thyroid bioassays performed. A second physician, the Assistant Director of Nuclear Medicine, failed at least 8 times to have required thyroid bioassays performed. There were 2 administrations where the nuclear medicine physician was not named on the record and no bioassay results were recorded. Thus far in 1996, 33 therapy doses have been administered. The Director of Nuclear Medicine/Radiation Safety Committee Chairman failed on at least 11 occasions, and the Assistant Director failed on at least 6 occasions to have thyroid bioassays performed. The nuclear medicine physician was not identified on 6 records and no bioassay results were noted. Although less frequently, a number of nuclear medicine technologists also failed to have bioassays performed following preparation and/or administration of therapeutic doses. The circumstances leading to and surrounding these repeated failures to perform a thyroid bioassay, including their causes, are still being reviewed by NRC staff and pending completion of the review, this matter is considered unresolved.

8.0 Radiological Safety Training

The licensee's radiation safety procedures require that training be conducted when changes occur in their procedures, conditions of the license, or the regulations. Also, 10 CFR 19.12 requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mR shall be instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Through personnel interviews, the inspector learned that about one year ago, a new device and probe used to measure the thyroid burden and uptake were placed into use. Individuals required to have a bioassay were required to use this device to measure their thyroid burden. At least 2 individuals required to have bioassays said that they had not been trained in the operation of the device and found it awkward to use the "new" probe.

Since measurement of thyroid burden is essential to monitoring the safe use and handling of iodine-131; and workers are expected to use the new unit and probe to measure their own thyroid burdens, the inspector concluded that failure to train workers in the operation of the bioassay unit and probe is a concern. The licensee stated that training will be given to all involved individuals prior to their next bioassay. The inspector stated that the circumstances leading to and surrounding this failure to train, including the cause, are still being reviewed by NRC staff and pending resolution of the review, this matter is considered unresolved.

9.0 Exit

At the conclusion of the inspection on September 19, 1996, the inspectors met with the individuals identified in Section 1.0 of this report and discussed the scope and initial findings of the inspection. The inspectors informed the licensee that the inspection findings were not closed because some information had yet to be reviewed.

On September 26, 1996, at the conclusion of personnel interviews and further records review, a second exit meeting was conducted. The inspectors met with the individuals identified in Section 1.0 of this report. The scope and findings of the inspection were discussed.